

Introduced by Senator Johnston

January 19, 2000

An act to amend Section 56.17 of the Civil Code, and to amend Section 124980 of the Health and Safety Code, relating to health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1364, as introduced, Johnston. Genetics: test disclosure.

Existing law, the Confidentiality of Medical Information Act, imposes prohibitions on the disclosure of the results of a test for a genetic characteristic contained in an applicant's or enrollee's medical records by a health care service plan.

This bill would specify, for those prohibitions, a definition for the term "genetic characteristic," that is the same as the definition contained in existing provisions regarding health care service plans.

Existing law requires the State Department of Health Services to recommend appropriate criteria and standards for licensing genetic counselors, and requires the department to consult with a group of medical experts representing medical professional organizations during the process of developing and recommending the criteria and standards. In addition, existing law requires the department to report its recommendations to the Legislature by January 1, 2000.

This bill would make a nonsubstantive change in that provision.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.



The people of the State of California do enact as follows:

1 SECTION 1. Section 56.17 of the Civil Code is
2 amended to read:

3 56.17. (a) This section shall apply to the disclosure of
4 genetic test results contained in an applicant's or
5 enrollee's medical records by a health care service plan.

6 (b) Any person who negligently discloses results of a
7 test for a genetic characteristic to any third party in a
8 manner that identifies or provides identifying
9 characteristics of the person to whom the test results
10 apply, except pursuant to a written authorization as
11 described in subdivision (g), shall be assessed a civil
12 penalty in an amount not to exceed one thousand dollars
13 (\$1,000) plus court costs, as determined by the court,
14 which penalty and costs shall be paid to the subject of the
15 test.

16 (c) Any person who willfully discloses the results of a
17 test for a genetic characteristic to any third party in a
18 manner that identifies or provides identifying
19 characteristics of the person to whom the test results
20 apply, except pursuant to a written authorization as
21 described in subdivision (g), shall be assessed a civil
22 penalty in an amount not less than one thousand dollars
23 (\$1,000) and no more than five thousand dollars (\$5,000)
24 plus court costs, as determined by the court, which
25 penalty and costs shall be paid to the subject of the test.

26 (d) Any person who willfully or negligently discloses
27 the results of a test for a genetic characteristic to a third
28 party in a manner that identifies or provides identifying
29 characteristics of the person to whom the test results
30 apply, except pursuant to a written authorization as
31 described in subdivision (g), that results in economic,
32 bodily, or emotional harm to the subject of the test, is
33 guilty of a misdemeanor punishable by a fine not to
34 exceed ten thousand dollars (\$10,000).

35 (e) In addition to the penalties listed in subdivisions
36 (b) and (c), any person who commits any act described
37 in subdivision (b) or (c) shall be liable to the subject for
38 all actual damages, including damages for economic,

1 bodily, or emotional harm which is proximately caused by
2 the act.

3 (f) Each disclosure made in violation of this section is
4 a separate and actionable offense.

5 (g) The applicant's "written authorization," as used in
6 this section, shall satisfy the following requirements:

7 (1) Is written in plain language.

8 (2) Is dated and signed by the individual or a person
9 authorized to act on behalf of the individual.

10 (3) Specifies the types of persons authorized to
11 disclose information about the individual.

12 (4) Specifies the nature of the information authorized
13 to be disclosed.

14 (5) States the name or functions of the persons or
15 entities authorized to receive the information.

16 (6) Specifies the purposes for which the information is
17 collected.

18 (7) Specifies the length of time the authorization shall
19 remain valid.

20 (8) Advises the person signing the authorization of the
21 right to receive a copy of the authorization. Written
22 authorization is required for each separate disclosure of
23 the test results.

24 (h) This section shall not apply to disclosures required
25 by the Department of Health Services necessary to
26 monitor compliance with Chapter 1 (commencing with
27 Section 124975) of Part 5 of Division 106 of the Health and
28 Safety Code, nor to disclosures required by the
29 Department of Managed Care necessary to administer
30 and enforce compliance with Section 1374.7 of the Health
31 and Safety Code.

32 (i) *For purposes of this section, "genetic*
33 *characteristic" has the same meaning as that set forth in*
34 *subdivision (d) of Section 1374.7 of the Health and Safety*
35 *Code.*

36 SEC. 2. Section 124980 of the Health and Safety Code
37 is amended to read:

38 124980. (a) The director shall establish any
39 regulations and standards for hereditary disorders
40 programs as the director deems necessary to promote and

1 protect the public health and safety, in accordance with
2 the principles established pursuant to this section. These
3 principles shall include, but not be limited to, the
4 following:

5 (1) The public, especially communities and groups
6 particularly affected by programs on hereditary
7 disorders, should be consulted before any regulations and
8 standards are adopted by the department.

9 (2) The incidence, severity, and treatment costs of
10 each hereditary disorder and its perceived burden by the
11 affected community should be considered and , where
12 appropriate, state and national experts in the medical,
13 psychological, ethical, social, and economic effects or
14 programs for the detection and management of
15 hereditary disorders shall be consulted by the
16 department.

17 (3) Information on the operation of all programs on
18 hereditary disorders within the state, except for
19 confidential information obtained from participants in
20 the programs, shall be open and freely available to the
21 public.

22 (4) Clinical testing procedures established for use in
23 programs, facilities, and projects shall be accurate,
24 provide maximum information, and the testing
25 procedures selected shall produce results that are subject
26 to minimum misinterpretation.

27 (5) No test or tests may be performed on any minor
28 over the objection of the minor's parents or guardian, nor
29 may any tests be performed unless the parent or guardian
30 is fully informed of the purposes of testing for hereditary
31 disorders and is given reasonable opportunity to object to
32 the testing.

33 (6) No testing, except initial screening for ~~PKU~~
34 *phenylketonuria (PKU)* and other diseases that may be
35 added to the newborn screening program, shall require
36 mandatory participation, and no testing programs shall
37 require restriction of childbearing, and participation in a
38 testing program shall not be a prerequisite to eligibility
39 for, or receipt of, any other service or assistance from, or
40 to participate in, any other program, except where

1 necessary to determine eligibility for further programs of
2 diagnoses of or therapy for hereditary conditions.

3 (7) Counseling services for hereditary disorders shall
4 be available through the program or a referral source for
5 all persons determined to be or who believe themselves
6 to be at risk for a hereditary disorder as a result of
7 screening programs; the counseling shall be nondirective,
8 emphasize informing the client, and shall not require
9 restriction of childbearing.

10 (8) All participants in programs on hereditary
11 disorders shall be protected from undue physical and
12 mental harm, and except for initial screening for ~~PKU~~
13 *phenylketonuria* (PKU) and other diseases that may be
14 added to newborn screening programs, shall be informed
15 of the nature of risks involved in participation in the
16 programs, and those determined to be affected with
17 genetic disease shall be informed of the nature, and
18 where possible the cost, of available therapies or
19 maintenance programs, and shall be informed of the
20 possible benefits and risks associated with these therapies
21 and programs.

22 (9) All testing results and personal information
23 generated from hereditary disorders programs shall be
24 made available to an individual over 18 years of age, or to
25 the individual's parent or guardian. If the individual is a
26 minor or incompetent, all testing results that have
27 positively determined the individual to either have, or be
28 a carrier of, a hereditary disorder shall be given through
29 a physician or other source of health care.

30 (10) All testing results and personal information from
31 hereditary disorders programs obtained from any
32 individual, or from specimens from any individual, shall
33 be held confidential and be considered a confidential
34 medical record except for information that the
35 individual, parent, or guardian consents to be released,
36 provided that the individual is first fully informed of the
37 scope of the information requested to be released, of all
38 of the risks, benefits, and purposes for the release, and of
39 the identity of those to whom the information will be
40 released or made available, except for statistical data

1 compiled without reference to the identity of any
2 individual, and except for research purposes, provided
3 that pursuant to Subpart A (commencing with Section
4 46.101) of Part 46 of Title 45 of the Code of Federal
5 Regulations entitled “Basic HHS Policy for Protection of
6 Human Subjects,” the research has first been reviewed
7 and approved by an institutional review board that
8 certifies the approval to the custodian of the information
9 and further certifies that in its judgment the information
10 is of such potentially substantial public health value that
11 modification of the requirement for legally effective
12 prior informed consent of the individual is ethically
13 justifiable.

14 (11) An individual whose confidentiality has been
15 breached as a result of any violation of the provisions of
16 the Hereditary Disorders Act, as defined in subdivision
17 (b) of Section 27, may recover compensatory damages
18 and, in addition, may recover civil damages not to exceed
19 ten thousand dollars (\$10,000), reasonable attorney’s fees,
20 and the costs of litigation.

21 (b) The department shall recommend appropriate
22 criteria and standards for licensing genetic counselors. In
23 the process of developing the recommended criteria and
24 standards, the department shall consult with a group of
25 medical experts representing medical professional
26 organizations including, but not limited to, the Medical
27 Board of California, the California Medical Association,
28 and organizations representing genetic counselors in
29 California. The department shall report its
30 recommendations to the Legislature by January 1, 2000.

